(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 480 667 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
20.03.1996 Bulletin 1996/12

(51) Int. Cl.[6]: **A61F 2/06**

(21) Application number: **91309197.1**

(22) Date of filing: **08.10.1991**

(54) Percutaneous stent assembly

Perkutane Stentanordnung

Dispositif dilatateur percutané

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

(30) Priority: **09.10.1990 US 594050**

(43) Date of publication of application:
15.04.1992 Bulletin 1992/16

(73) Proprietor: **Cook Incorporated**
Bloomington Indiana 47401 (US)

(72) Inventor: **Gianturco, Cesare**
Champaign, Illinois 61821 (US)

(74) Representative: **Dempster, Benjamin John Naftel et al**
Withers & Rogers
4 Dyer's Buildings,
Holborn
London EC1N 2JT (GB)

(56) References cited:

EP-A- 0 119 688	EP-A- 0 335 341
WO-A-89/08433	DE-A- 3 417 738
DE-A- 3 918 736	FR-A- 1 602 513

- **THE LANCET vol. 335, no. 8689, 10 March 1990, LONDON pages 582 - 584; P.J.M. GEORGE ET AL.: 'COVERED EXPANDABLE STENTS FOR RECURRENT TRACHEAL OBSTRUCTION'**

EP 0 480 667 B1

Printed by Rank Xerox (UK) Business Services
2.9.12/3.4

AL4

Description

This invention relates generally to vascular stents for use in preventing restenosis of passageways and ducts in the body and to repair aneurysms percutaneously.

It is desirable that means be provided which will prevent the restenosis of a passage or duct due to the invasion of tissue between the wire struts of the stent. Such a situation often occurs where a tumor has invaded a biliary tract. In those cases, a wire stent tends to provide only temporary relief from occlusion because the tumor often tends to grow between the wire struts, eventually resulting in a restenosed passageway. Gianturco U.S. Pat. No. 4,580,568 exemplifies such conventional wire stents. While Gianturco '568 discloses a wire stent to reduce flow defects in arteries, ducts and the like within the body, it does not solve the problem of tissue growth between the wire struts of the stent. Thus, conventional wire stents do not necessarily provide an acceptable long-term solution in the face of malignant tissue growth, nor do such stents provide a means to repair aneurysms percutaneously.

Reference is also made to U.S. Patent Application Serial No. 422,606, also by Gianturco. That application teaches a stent structure and method which permits a stent to be easily retrieved from the body percutaneously, some time after being successfully implanted. In many instances, such an advantage would be suitable to the present invention.

There remains a need for a percutaneous stent assembly that is self-expanding, yet is capable of preventing or reducing restenosis. There is also need for a percutaneous stent assembly which is capable of repairing aneurysms.

An article in "The Lancet", vol. 335, No. 8689 of 10th march 1990, London pages 582 to 584 is entitled "covered expandable metal stent for recurrent tracheal obstruction" and is by P.J.M. George, J.D. Irving, B.S. Mantell and R.M. Rudd. The article discloses the use of a "Gianturco" stainless steel wire stent which was covered with a material made from nylon and polyvinylchloride. The stent was compressed and loaded into a hollow delivery catheter and introduced into a patient's lung through a rigid bronchoscope. The patient had an intraluminal tumour causing a tracheal obstruction.

According to the invention there is provided a percutaneous stent assembly comprising:

a flexible sleeve having an inner surface and an outer surface and being open at both ends;

two resiliently compressible stents, each of said stents including a plurality of struts and defining a series of gaps between said struts;

wherein said percutaneous stent assembly defines a smaller first shape when elastically compressed and a larger second shape when allowed to expand; characterised in that

a rigid support rod is positioned between said stents and has opposite ends;

each of said stents is connected to a respective one of said ends of said rigid support rod;

each of said stents is attached to said flexible sleeve such that said stents and said rigid support rod are substantially covered by said flexible sleeve;

and wherein said struts and said rigid support rod render said percutaneous stent assembly resistant to contraction along the axis defined by said rigid support rod.

The smaller first shape allows the assembly to be passed percutaneously through a lumen into a passageway within the body. Upon implantation, the sleeved stent assembly is allowed to expand to assume the second larger shape wherein the flexible sleeve is pressed against the walls of the passageway by the stents to the maintain the passageway open.

One object of the present invention is to provide an improved percutaneous stent assembly.

Related objects and advantages of the present invention will be apparent from the following description.

Fig. 1 is a sectioned side elevation of a preferred embodiment of the present invention; and

Fig. 2 is a sectioned side elevation of the structure of Fig. 1 implanted to span an aneurysm in an artery.

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to an embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

An embodiment of the present invention, which is particularly suited for repairing aneurysms percutaneously, is illustrated in Fig. 1. The percutaneous stent assembly 50 includes resiliently expandable stents 51 and 52, rigid support rod 53 and nylon sleeve 54. Stents 51 and 52 are formed from a length of stainless steel wire formed in a closed zig-zag configuration. The ends of the wire can be closed in a variety of ways, including the use of a sleeve which is welded or tightly pinched against the ends of the wire to produce a continuous or endless configuration. Each stent 51 and 52 comprises a plurality of struts 14 connected to one another by a series of joints. In most respects, stents 51 and 52 are similar to the Z-stent described in US Patent No. 4590568 (Gianturco '568), which description is incorporated herein by reference. Each serial pair of struts 14 defines a gap 16 therebetween. The stents 51 and 52 are attached to sleeve 54 by stitching or gluing the joints 55, which are located at either end of the assembly, to the inner surface 56 of the sleeve. If the sleeve were made of plastic, the stents could be attached to the sleeve by embedding the stents in the plastic, it being understood that the means for attaching the stents to the sleeve can be varied depend-

ing on the sleeve material, and other factors, without diverging from the intended scope of the present invention.

During implantation, the rigid support rod 53 prevents the percutaneous stent assembly 50 from collapsing on itself along the axis defined by sleeve 54. This embodiment is implanted at the desired point in the body as described earlier for the previous embodiment. Fig. 3 shows stent assembly 50 after being implanted in an artery having an aneurysm. The stent assembly is secured in place when stents 51 and 52 press the sleeve 54 against the undamaged walls of the artery located on either side of the aneurysm. The sleeve 54 then forms an artificial arterial wall that spans the aneurysm. This removes pressure from the aneurysm, allowing it to heal.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the scope of the claims are desired to be protected.

Claims

1. A percutaneous stent assembly (50) comprising:
   a flexible sleeve (54) having an inner surface and an outer surface and being open at both ends;
   two resiliently compressible stents (51,52), each of said stents (51,52) including a plurality of struts (14) and defining a series of gaps (16) between said struts (14);
   wherein said percutaneous stent assembly (50) defines a smaller first shape when elastically compressed and a larger second shape when allowed to expand; characterised in that
   a rigid support rod (53) is positioned between said stents (51,52) and has opposite ends;
   each of said stents (51,52) is connected to a respective one of said ends of said rigid support rod (53);
   each of said stents (51,52) is attached to said flexible sleeve (54) such that said stents (51, 52) and said rigid support rod (53) are substantially covered by said flexible sleeve (54);
   and wherein said struts (14) and said rigid support rod (53) render said percutaneous stent assembly (50) resistant to contraction along the axis defined by said rigid support rod (53).

2. The percutaneous stent assembly of claim 1, wherein said flexible sleeve (54) is made of nylon.

3. The percutaneous stent assembly of claim 1 or claim 2, wherein each of said stents (51,52) is attached to said flexible sleeve by a plurality of stitches.

4. The percutaneous stent assembly of claim 1, wherein said flexible sleeve (54) is made of plastic.

5. The percutaneous stent assembly of claim 4, wherein each of said stents (51,52) is attached to said flexible sleeve (54) by embedding said stents (51,52) in said plastic.

6. The percutaneous stent assembly of any preceding claim, further comprising a plurality of rigid support rods (53) positioned parallel to one another and between each said stent (51,52);
   wherein each respective end of each said rigid support rod (53) is attached to one said stent (51,52).

Patentansprüche

1. Perkutane Stentanordnung (50), welche folgendes aufweist:
   eine flexible Hülse (54), welche eine innere Fläche und eine äußere Fläche hat und an beiden Enden offen ist;
   zwei federnd nachgiebige, kompressible Stents (51, 52), wobei jeder der Stents (51, 52) eine Mehrzahl von strebenförmigen Absteifungen (14) umfaßt und zwischen den strebenförmigen Absteifungen (14) eine Reihe von Zwischenräumen (16) gebildet wird;
   bei der die perkutane Stentanordnung (50) eine kleinere, erste Gestalt hat, wenn sie zusammengedrückt wird, und eine größere, zweite Gestalt hat, wenn sie sich expandieren kann, **dadurch gekennzeichnet**, daß
   ein starrer Tragstab (53) zwischen den Stents (51, 52) angeordnet ist, welcher gegenüberliegende Enden hat;
   jeder der Stents (51, 52) mit einem zugeordneten Ende des starren Tragstabs (53) verbunden ist;
   jeder der Stents (51, 52) an der flexiblen Hülse (54) derart angebracht ist, daß die Stents (51, 52) und der starre Tragstab (53) im wesentlichen durch die flexible Hülse (54) bedeckt sind;
   und bei der die strebenförmigen Absteifungen und der starre Tragstab (53) der perkutanen Stentanordnung (50) einen Widerstand gegenüber einer Kontraktion entlang der Achse verleihen, welche durch den starren Tragstab (53) bestimmt ist.

2. Perkutane Stentanordnung nach Anspruch 1, bei der die flexible Hülse (54) aus Nylon hergestellt ist.

3. Perkutane Stentanordnung nach Anspruch 1 oder 2, bei der jeder der Stents (51, 52) an der flexiblen Hülse über eine Mehrzahl von Stichen angebracht ist.

4. Perkutane Stentanordnung nach Anspruch 1, bei der die flexible Hülse (54) aus Kunststoff hergestellt ist.

5. Perkutane Stentanordnung nach Anspruch 4, bei der jede der Stents (51, 52) an der flexiblen Hülse (54) dadurch angebracht ist, daß die Stents (51, 52) in den Kunststoff eingebettet sind.

6. Perkutane Stentanordnung nach einem der vorangehenden Ansprüche, welche ferner eine Mehrzahl von starren Tragstäben (53) aufweist, welche parallel zueinander und zwischen jedem der Stents (51, 52) angeordnet ist,

wobei jedes zugeordnete Ende des jeweiligen Tragstabs (53) an einer der Stents (51, 52) angebracht ist.

Revendications

1. Dispositif dilatateur percutané (50), comprenant :

un fourreau souple (54) ayant une face interne et une face externe, et ouvert aux deux extrémités ;

deux dilatateurs élastiquement compressibles (51, 52), chacun desdits dilatateurs (51, 52) comprenant une pluralité d'entretoises (14) et définissant une série d'écartements (16) entre lesdites entretoises (14) ;

dans lequel ledit dispositif dilatateur percutané (50) définit une première forme, plus petite, lorsqu'il est élastiquement comprimé, et une seconde forme, plus grande, lorsqu'il peut se dilater ; caractérisé en ce que

une tige-support rigide (53) est placée entre lesdits dilatateurs (51, 52) et présente des extrémités opposées ;

chacun desdits dilatateurs (51, 52) est relié à une extrémité respective desdites extrémités de ladite tige-support rigide (53) ;

chacun desdits dilatateurs (51, 52) est fixé audit fourreau souple (54) de telle manière que lesdits dilatateurs (51, 52) et ladite tige-support rigide (53) soient sensiblement recouverts par ledit fourreau souple (54) ;

et dans lequel lesdites entretoises (14) et ladite tige-support rigide (53) rendent ledit dispositif dilatateur percutané (50) résistant à la contraction suivant l'axe défini par ladite tige-support rigide (53).

2. Dispositif dilatateur percutané selon la revendication 1, dans lequel ledit fourreau souple (54) est fait en Nylon.

3. Dispositif dilatateur percutané selon la revendication 1 ou la revendication 2, dans lequel chacun desdits dilatateurs (51, 52) est fixé audit fourreau souple par une pluralité de points de couture.

4. Dispositif dilatateur percutané selon la revendication 1, dans lequel ledit fourreau souple (54) est fait en matière plastique.

5. Dispositif dilatateur percutané selon la revendication 4, dans lequel chacun desdits dilatateurs (51, 52) est fixé audit fourreau souple (54) par encastrement desdits dilatateurs (51, 52) dans ladite matière plastique.

6. Dispositif dilatateur percutané selon l'une quelconque des revendications précédentes, comprenant en outre une pluralité de tiges-supports rigides (53) disposées parallèlement les unes aux autres et entre chaque dilatateur (51, 52) ;

dans lequel chaque extrémité respective de chaque tige-support rigide (53) est fixée à l'un desdits dilatateurs (51, 52).

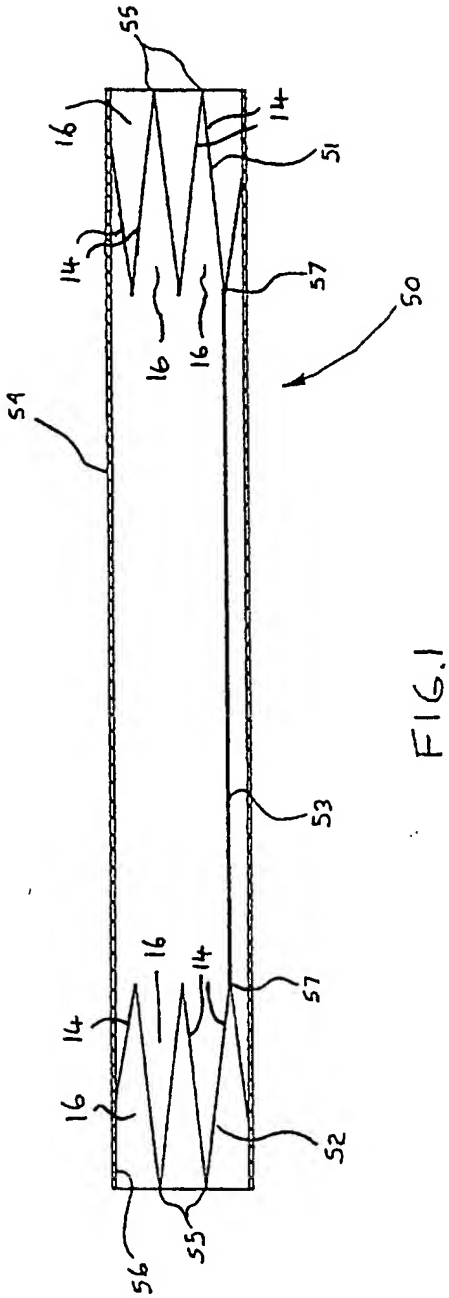

FIG.1

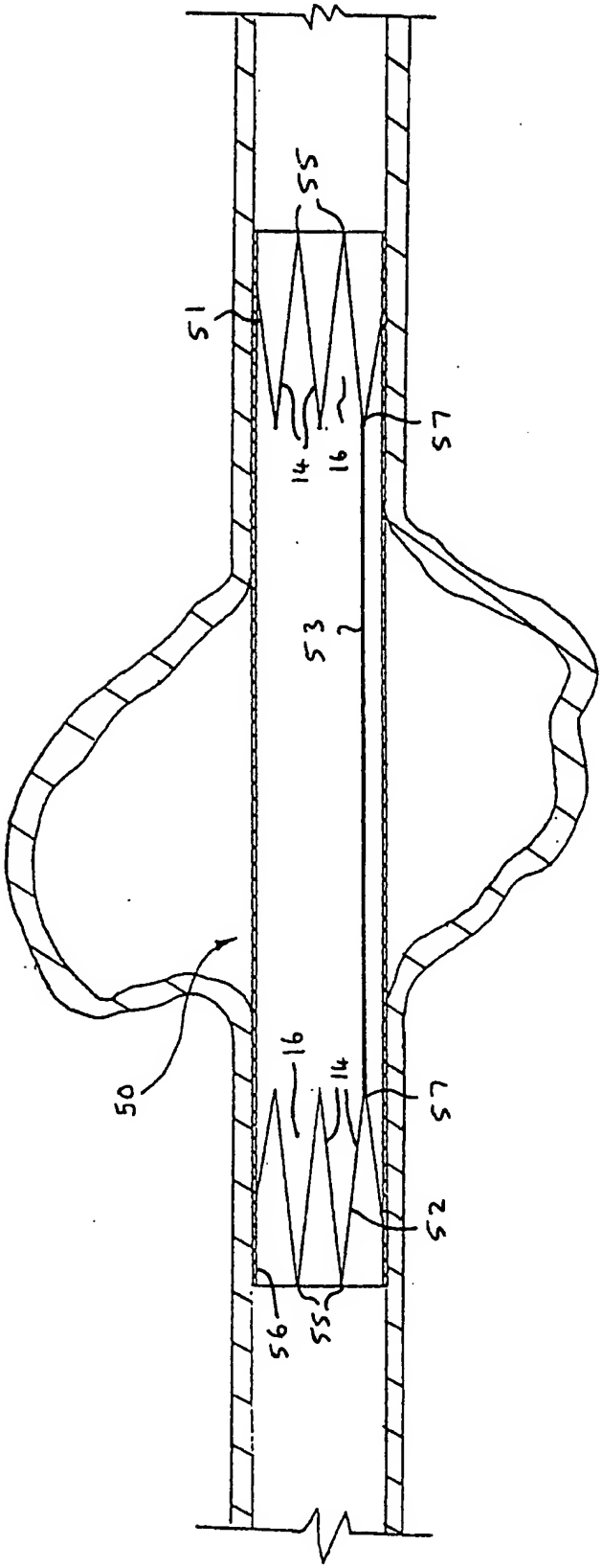

FIG.2